3. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

APPLICANT	OrthAlign, Inc. 120 Columbia Suite 500 Aliso Viejo, CA 92656 Tel: (949) 715-2424 Fax: (949) 831-9500
OFFICIAL CORRESPONDENT	Amy Walters AWE, Inc. 338 Vista Madera Newport Beach, CA 92660 amylynnwalters@gmail.com Tel: (949) 923-9400 Fax: (949) 831-9500
TRADE NAME	OrthAlign Plus™ System
COMMON NAME	Stereotaxic Instrument
DEVICE CLASSIFICATION	Class II, 21 CFR §882.4560
PRODUCT CODES	OLO: Orthopedic Stereotaxic Instrument
PREDICATE DEVICES	KneeAlign® 2 System (K103829) Navitrack System - S&N Image Free Knee (K043536) Navitrack System - S&N Image Free Hip (K041369)
SUBMISSION TYPE	Traditional 510(k). The subject device is a modification to the previously cleared KneeAlign® 2 System (K103829).

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SUBSTANTIALLY EQUIVALENT TO:

The OrthAlign Plus™ System is substantially equivalent to the previously cleared KneeAlign® 2 System (K103829), Navitrack System - S&N Image Free Hip (K041369) and Navitrack System- S&N Image Free Knee (K043536).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OrthAlign Plus™ System is an innovative non-invasive computer assisted surgical navigation system for use in knee and hip arthroplasty procedures. The OrthAlign Plus™ System is configured to detect, measure, and display angular and positional measurement changes in a triaxial format.

The current standard of care for knee arthroplasty procedures has the physician estimating these changes either by visual observation and mechanical guides with tactile feedback or with assistance of computer assisted surgery devices.

The current standard of care for hip arthroplasty procedures has the physician estimating angular orientation of the acetabular shell either by visual observation and mechanical guides or with assistance of computer assisted surgery devices.

The OrthAlign Plus™ System utilizes a palm-sized computer module and reference sensor to generate positional information in orthopedic procedures, providing a sequence of steps for registration of anatomical landmarks, calculation of mechanical axes, and positioning of instruments relative to the mechanical axes.

In knee arthroplasty procedures, the device assists the surgeon in:

- Establishing the mechanical axis of the femur, determining the varus/valgus angle and the flexion/extension angle of the cutting block relative to femur.
- Establishing the mechanical axis of the tibia, determining the varus/valgus angle and the posterior slope angle of the cutting block relative to tibia.

In hip arthroplasty procedures, the device assists the surgeon in:

- Establishing the orientation of the anterior pelvic plane and determining the inclination angle and the anteversion angle of the shell impactor relative to the anterior pelvic plane.

The OrthAlign Plus™ System comprises a single use computer module and reusable instrumentation.

The OrthAlign Plus™ System is usable for a total knee arthroplasty or total hip arthroplasty procedure. The System includes two optional configurations: the KneeAlign® 3 System usable for total knee arthroplasty only, and the HipAlign® System usable for total hip arthroplasty only. The OrthAlign Plus™ System includes the single-use OrthAlign Plus™ Unit, a KneeAlign® 3 Instrument Set and a HipAlign® Instrument Set. The optional configurations include a modified version of the OrthAlign Plus™ Unit and only one of the Instrument Sets. Indications for Use for each optional configuration are limited to the applicable orthopedic procedure.

INDICATIONS FOR USE:

The OrthAlign Plus™ System has the same indications for use as the previously cleared KneeAlign® 2 System (K103829). Additional functionality has been added to the predicate device to enable navigation for Total Hip Arthroplasty. Also, Indications for Use are common to the Navitrack System- S&N Image Free Hip (K041369) and Navitrack System- S&N Image Free Knee (K043536). Thus, the Indications for Use are as follows:

OrthAlign Plus™ System:

The OrthAlign Plus™ System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The OrthAlign Plus™ System facilitates the accurate positioning of implants, relative to these alignment axes.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty
- Total Hip Arthroplasty: Anterior / Posterior

KneeAlign® 3 System:

The KneeAlign® 3 System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The KneeAlign® System facilitates the accurate positioning of implants, relative to these alignment axes.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty

HipAlign® System:

The HipAlign™ System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The HipAlign® System facilitates the accurate positioning of implants, relative to these alignment axes.

Example orthopedic surgical procedures include but are not limited to:

- Total Hip Arthroplasty: Anterior / Posterior

TECHNICAL CHARACTERISTICS:

The OrthAlign Plus™ System comprises a single use computer module, a reusable reference sensor, a reusable femoral jig, a reusable tibial jig, a reusable posterior hip jig and a reusable anterior hip jig. The device utilizes algorithms to convert sensor outputs into spatial coordinates, providing graphical and numerical representation of instruments and anatomy on the user display screen.

The optional KneeAlign® 3 and HipAlign® system configurations also comprise the single use computer module, reusable reference sensor and applicable reusable jigs. They utilize the same algorithms, sensor conversions, graphical and numerical representations and surgical techniques as the OrthAlign Plus™ System.

The terms "OrthAlign Plus™ System" and "OrthAlign Plus™ Unit" are used henceforth in this submission to refer to all three system configurations and all three single-use computer modules, except where all three configurations are cited and differentiated.

PERFORMANCE DATA:

Device performance testing confirms that the OrthAlign Plus™ System can be used according to its intended use. The OrthAlign Plus™ System has been verified and validated according to OrthAlign's procedures for product design and development. Performance testing included:

- Software verification and validation
- System hardware verification and validation testing
- Electrical safety and electromagnetic compatibility testing
- Instrumentation cleaning, sterilization and shipping validations
- System components biocompatibility assessment
- Customer requirements validation
- System accuracy testing: bench testing with mechanical fixtures and foam models
- Simulated use testing: cadaver and virtual testing

For simulated use testing, a prospective cadaver validation was done with a series of 3 labs in a simulated operating room environment with 3 surgeons conducting the procedures, both anterior and posterior approaches. A follow-up virtual study was conducted on the system's navigation in the posterior approach with software updates applied to the earlier testing.

Navigation of cup angles in the anterior approach was validated in a series of 2 cadaver labs with 30 specimens (30 hips), using radiographic evaluation of the cup placements.

Navigation of cup angles in the posterior approach was validated in a series of 2 cadaver labs with 12 full body specimens (18 hips), using radiographic evaluation of cup placements and a follow-up virtual study of navigation with software updates applied.

This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate devices, for its intended use in facilitating the accurate positioning of implants and instrumentation, relative to reference alignment axes.

The information provided by OrthAlign in this 510(k) application confirms that the OrthAlign Plus™ System is substantially equivalent to predicate devices: KneeAlign® 2 System (K103829), Navitrack System- S&N Image Free Knee (K043536) and Navitrack System- S&N Image Free Hip (K041369).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison and bench and cadaver testing demonstrate the substantial equivalence of the OrthAlign Plus™ System to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 8, 2013

OrthAlign, Incorporated
% Ms. Amy Walters
AWE, Incorporated
338 Vista Madera
Newport Beach, California 92660

Re: K130387
Trade/Device Name: OrthAlign Plus™ System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 25, 2013
Received: October 1, 2013

Dear Ms. Walters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE STATEMENT

2.1. ORTHALIGN PLUS™ SYSTEM

510(k) Number (if known): K130387

Device Name: OrthAlign Plus™ System

Indications for Use:

The OrthAlign Plus™ System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The OrthAlign Plus™ System facilitates the accurate positioning of implants, relative to these alignment axes.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty
- Total Hip Arthroplasty: Anterior / Posterior

Prescription Use __x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

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for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130387

2.2. KNEEALIGN® 3 SYSTEM

510(k) Number (if known): K130387

Device Name: KneeAlign® 3 System

Indications for Use:

The KneeAlign® 3 System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The KneeAlign® 3 System facilitates the accurate positioning of implants, relative to these alignment axes.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130387

2.3. HIPALIGN® SYSTEM

510(k) Number (if known): K130387

Device Name: HipAlign® System

Indications for Use:

The HipAlign® System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The HipAlign® System facilitates the accurate positioning of implants, relative to these alignment axes.

Example orthopedic surgical procedures include but are not limited to:

- Total Hip Arthroplasty: Anterior / Posterior

Prescription Use __x__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

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Division of Surgical Devices
510(k) Number: K130387